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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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STITES & HARBISON, PLLC
400 W MARKET ST
SUITE 1800
LOUISVILLE, KY 40202-3352

EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

T4

Office Action Summary	Application No.	Applicant(s)	
	10/660,841	SMITH, C. STEVEN	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-77* is/are pending in the application.

4a) Of the above claim(s) *46-63 and 73-77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45 and 64-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Response and Amendment after Non-Final Office Action, Applicant's Arguments/Remarks and the request for extension of time (2 months-granted), all filed 10/19/06 is acknowledged. Examiner also acknowledges Applicant's request to rejoin newly added method claims 73-77, presumed withdrawn, upon allowance of the elected composition claims.

Newly submitted claims 73-77 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly submitted claims (73-77) are method claims that depend upon and contain subject matter of previously withdrawn, non-elected claims (46-63).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 73-33 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant has overcome the following rejection(s) by virtue of the amendment filed 10/19/06:

(1) The 35 U.S.C. §112, 1st paragraph rejection of claims 1-45 has been withdrawn, based on the deletion of the term "prevention".

(2) The 35 U.S.C. §102(e) anticipation rejection of claims 1, 2, 5, 6, 8-10, 13, 26, 29, 30 and 33-43 over Osbakken *et al.* (U.S. Pat. Publication No. 2002/0061281) has been withdrawn.

(3) The 35 U.S.C. §103(a) obviousness rejection of claims 1, 2, 5, 6 and 8-43 over Osbakken *et al.* (U.S. Pat. Publication No. 2002/0061281) has been withdrawn.

Claims 1-77 are pending in this action. Claims 1, 3-5, 7, 46, 48-50 and 52 have been amended. New claims 64-77 have been added. Claims 46-63 and 73-77 have been withdrawn. Claims 1-45 and 64-72 are rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-45 and 64-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osbakken *et al.* (U.S. Pat. Publication No. 2002/0061281 A1) in view of Gray (U.S. Pat. No. 5,698,558) and further in view of Fust (U.S. Pat. No. 6,344,210).

The instant invention is drawn to a composition useful for the non-addictive treatment of rhinitis in a subject, the composition comprising effective amounts of a suitable nasal decongestant; a suitable corticosteroid; and a suitable anticholinergic agent.

Osbakken *et al.* ('281), as delineated above, teach pharmaceutical compositions that comprise one or more active ingredients selected from the group consisting of anti-infective agents, anti-inflammatory agents (including steroidal and non-steroidal anti-inflammatory agents), mucolytic agents, anthistamines, antileukotrienes, decongestants, anticholinergic agents,

antifungal agents and a combination of these classes of agents (see reference page 6, ¶ 69); (Table 1 at pp. 15-17). The compositions are formulated as a liquid (solution, suspension, emulsion, etc.) or a powder that can be mixed with a diluent to produce a liquid for administration to the nasal sinuses. The formulations can be used in the treatment of sinusitis (page 6, ¶ 70).

Suitable steroidal anti-inflammatories taught include: betamethasone, triamcinolone, dexamethasone, prednisone, mometasone, fluticasone, beclomethasone, flunisolide and budesonide. The anti-inflammatories have a wide range of inhibitory activities against multiple cell types (e.g., leukotrienes, cytokines) (pg. 10, ¶ 138-145).

Suitable decongestants taught include: phenylpropanolamine, pseudoephedrine, phenylephrine, epinephrine, ephedrine and oxymetazoline (pg. 6 ¶ 74; pg. 10 ¶ 146-150).

Suitable anticholinergics taught include: ipratropium, atropine and scopolamine (pg. 6 ¶ 74; pg.10 ¶ 156-159).

Leukotriene receptor antagonists are also disclosed and include: zafirlukast, montelukast, pranlukast, iralukast and pobilukast (pg.9 ¶ 124-126).

Antihistamines are also disclosed and include: diphenhydramine, astemizole and terfenadine (pg. 9 ¶ 128-131).

Anti-infective agents are disclosed and include: penicillins, cephalosporins, macrolides, ketolides, sulfonamides and the like (pg. 11 ¶ 170).

Cromolyn and nedocromil sodium are disclosed at Table 1 (pp. 16-17).

With regards to the instantly claimed amounts and/or ranges, Osbakken *et al.* do not explicitly teach the claimed amounts and/or ranges. However, the Examiner points out that

generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, prior art teaches the incorporation of the same components, particularly, decongestants, corticosteroids and anticholinergics for use in the same field of endeavor and to treat the same disorders, such as upper respiratory conditions, as claimed by Applicant. Moreover, it is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts/ranges through the use of routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. Furthermore, Applicants have not demonstrated any unexpected and/or superior results attributable to the claimed amounts/ranges. The prior art vividly recognizes and teaches suitable pharmaceutical compositions for effectively treating respiratory disorders and conditions.

Osbakken *et al.* teach upper airway conditions, such as sinusitis. Osbakken *et al.* do not explicitly teach rhinitis and pharyngitis.

Gray ('558) teaches compositions comprising cetirizine that are useful in treating allergic rhinitis and pharyngitis (see reference column 1, lines 10-33); (col. 2, lines 14-38). The compositions possess potent activity in treating seasonal and perennial allergic rhinitis and avoid adverse anticholinergic effects, gastrointestinal disturbance, headaches and cardiovascular effects (col. 1, lines 13-33). The reference recognizes that allergic rhinitis is characterized by symptoms

such as pharyngitis. The reference also teaches that, for most patients, topical corticosteroids provide relief from rhinitis symptoms (col. 2, lines 31034). The compositions include suspensions, solutions, elixirs, aerosols or solid dosage forms (col. 7, lines 15-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the rhinitis- and pharyngitis- treating compositions taught by Gray within the pharmaceutical compositions of Osbakken *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Gray explicitly teaches that the compositions comprising cetirizine are effective for treating (allergic) rhinitis, as well as symptoms arising from (allergic) rhinitis, such as pharyngitis and also teach that the compositions avoid any adverse effects, such as anticholinergic effects. The expected result would be an improved pharmaceutical composition that is beneficial for treating various upper respiratory conditions in a subject.

Osbakken *et al.* ('281), as delineated above, teach pharmaceutical compositions that comprise one or more active ingredients selected from the group consisting of anti-infective agents, anti-inflammatory agents (including steroidal and non-steroidal anti-inflammatory agents), mucolytic agents, anthistamines, antileukotrienes, decongestants, anticholinergic agents, antifungal agents and a combination of these classes of agents (see reference page 6, ¶ 69); (Table 1 at pp. 15-17). The compositions are formulated as a liquid (solution, suspension, emulsion, etc.) or a powder that can be mixed with a diluent to produce a liquid for administration to the nasal sinuses. The formulations can be used in the treatment of sinusitis (page 6, ¶ 70).

Osbakken *et al.* do not teach an aromatic agent (*i.e.*, camphor, menthol, eucalyptus).

Fust ('210) teaches compositions for freshening nostrils and sinus cavities comprising aromatic agents such as menthol and eucalyptol (see reference column 1, line 20 – col. 2, line 52); (col. 4, lines 5-10); (col. 8, lines 24-27) and Examples.

Fust teaches that the freshening ingredients of the composition leaves the nose and sinuses feeling cleansed, cleared and refreshed with a minty after-taste (col. 21-25).

The compositions are especially effective for persons with sinusitis and rhinitis, which result in a temporary loss of smell; the same effect that may stem from a number of allergies, all of which are associated with nasal congestion (col. 2, lines 42-52).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate aromatic agents, such as menthol and eucalyptol as taught by Fust within the pharmaceutical compositions of Osbakken *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Fust explicitly teaches that the freshening ingredients of the composition leaves the nose and sinuses feeling cleansed, cleared and refreshed with a minty after-taste, thus eliminating and masking objectionable odors. The expected result would be an aromatic-enhanced pharmaceutical composition that provides for cleaner and healthier nasal and sinus passageways.

Pertinent Art

Prior Art made of record, not relied upon and deemed relevant by Examiner:

- Sequeira *et al.* (U.S. Pat. No. 5,889,015)

Sequeira *et al.* teach mometasone furoate for treating corticosteroid-responsive diseases of the surfaces of upper and/or lower airway passages and/or lungs, e.g. allergic rhinitis (see Abstract).

Response to Arguments

Applicant's arguments filed 10/19/06 have been fully considered and were found to be partially persuasive.

1. 35 U.S.C. §112, 1st paragraph rejection:

Applicant argued, "The Examiner objected to claims 1-45 pursuant to 35 U.S.C. §112 as not being enabled based on their recitation of the word, prevention. Applicant has addressed this concern by removing the term "prevention" as suggested by the Examiner."

Applicant's arguments have been fully considered and were found persuasive by virtue of the amendment deleting the term "prevention". Accordingly, the 35 U.S.C. §112, 1st paragraph rejection of claims 1-45 has been withdrawn.

2. 35 U.S.C. §102(e) and §103(a) rejection over Osbakken:

Applicant argued, "This Response will now address the rejections based on the '281 Publication as an independent reference. Original claims 3 and 7 were not included in either the anticipation rejection or the obviousness rejection based on the '281 Publication. Claims 1, 2, and 10-43 have been amended to include the limitations of original claim 3. Claims 5, 6, 8, and 9 have been amended to include limitations from claim 7. As such, it is

respectfully requested that rejection of the claims pursuant to §§102 and 103 based on the '281 Publication as an independent reference be withdrawn."

Applicant's arguments have been fully considered and were found persuasive by virtue of the amendment to the claims. Accordingly, the 35 U.S.C. §102(a) rejection of claims 1, 2, 5, 6, 8-10, 13, 26, 29, 30 and 33-43 over Osbakken *et al.* (U.S. Pat. Publication No. 2002/0061281) and the 35 U.S.C. §103(a) rejections of claims 1, 2, 5, 6 and 8-43 over Osbakken *et al.* ('281) have been withdrawn.

However, the Osbakken ('281) Publication has now been combined under 35 U.S.C. §103(a) with the Gray ('558) patent.

3. 35 U.S.C. §103(a) rejection over Osbakken in view of Gray ('558):

Applicant argued, "The '281 Publication describes compositions and methods for treating chronic sinusitis, which is an 'inflammation of the membrane lining one or more paranasal sinuses....which lasts longer than three weeks and often continues for months.' Sinusitis differs from rhinitis; it has distinct pathology and is a distinct condition. Pending claim 1, on the other hand, are directed towards a non-addictive composition for treating rhinitis. Other embodiments of the claimed invention are directed towards a non-addictive composition for treating pharyngitis. The Examiner's statement merely provides information about the teaching of the '558 patent; it does not provide evidence to establish any motivation to combine the '558 patent and the '281 Publication. It is critical to the '281 Publication that a particular surface tension and particle size be delivered, to allow for the particles to enter the sinuses, the site of inflammation and infection that defines the condition of sinusitis. Specific delivery of a topical treatment to the sinuses would serve to affect treatment of sinusitis, but it would not effectively treat rhinitis because it would not be acting at the appropriate site of the rhinitis-associated inflammation. In this regard, the '281 Publication teaches away from compositions for

treating rhinitis. Furthermore, the '281 device produces an air flow capable of causing non-allergic rhinitis in susceptible subjects."

Applicant's arguments have been fully considered, but were not persuasive. Admittedly, while the primary '281 Publication does not teach treatment of 'rhinitis', the secondary '558 provides ample motivation to treat conditions of rhinitis, as well as pharyngitis.

Both diseases, namely, sinusitis and rhinitis are diseases that prevent airflow in a subject. Both diseases are directed to build up of mucus and both diseases are directed to inflammatory conditions.

Although the causes of the diseases are different, both are considered infections in which the art recognizes would be treated with antibiotics and anti-inflammatory agents. It is the position of the Examiner that the diseases would be sufficiently related as to render one obvious over the other. Both diseases are recognized as occurring within the same patient population, *i.e.*, the general public. Neither disease is specific to a distinguished patient population. Thus, the combined reference teachings meet the limitations of the claims.

4. **35 U.S.C. §103(a) rejection over Osbakken in view of Fust ('210):**

Applicant argued, "The Examiner's statement merely provides information about the teaching of the '210 patent; it does not provide evidence to establish any motivation to combine the '210 patent and the '281 Publication. There is not any convincing line of reasoning that is provided to explain how an 'explicit teaching that the freshening ingredients of the composition leaves the nose and sinuses feeling cleansed...with a

minty after-taste' would motivate one of ordinary skill in the art to select the '210 patent, then select the '281 Publication and then combine them to create the claimed invention.' The '281 Publication fails to teach compositions for treating rhinitis and fails to teach compositions including an aromatic agent. The '210 Patent is directed towards a composition for 'freshening sinus cavities', not a composition directed towards the treatment of rhinitis."

Applicant's arguments have been fully considered and were found partially persuasive. The rejection has now been reformulated as a §103(a) rejection over Osbakken ('281) in view of Gray ('558) and further in view of Fust ('210). While the Fust reference does not explicitly teach treatment of rhinitis, the secondary reference of Gray demonstrates compositions used in the treatment of rhinitis, as well as pharyngitis. The Fust reference has been cited to show that the use of aromatic agents such as menthol and eucalyptol in compositions for freshening nostrils and sinus cavities is well known. The Fust reference emphasizes employing the compositions to the sinus cavities, rather than nasal passageways. However, the Examiner points out although the causes of sinusitis and rhinitis may be of a different origin, both diseases are directed to build up of mucus and both diseases are directed to inflammatory conditions. Both diseases, as discussed above, are considered infections in which the art recognizes would be treated with antibiotics and anti-inflammatory agents. Both diseases are recognized as occurring within the same patient population, *i.e.*, the general public and neither disease is specific to a distinguished patient population. The prior art vividly recognizes and teaches similar components, particularly, aromatic agents used for the same field of endeavor as that desired by Applicant.

Thus, the instantly claimed limitations have been fully met by the combined reference teachings cited above. It remains the position of the Examiner that the instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 46-63 and 73-77 drawn to an invention nonelected with traverse in the Response to Restriction filed 04/05/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

January 04, 2007

HUMERA N SHEIKH
PRIMARY EXAMINER
TC-1600

hns